Application No. 09/706,507 Filed: November 3, 2000

## REMARKS

## A. The Sequence Listing Rules Should Be Waived With Respect To The Present Application

The present application is a continuation of U.S. patent application serial no. 08/484,893, now U.S. Patent No. 6,172,197 B1 (the '197 patent, "parent application"), which was a continuation of U.S. patent application serial no. 07/971,857, now U.S. Patent No. 5,969,108 (the '108 patent, "grandparent application"), which was the U.S. national stage of PCT/GB91/01134 (the '01134 application). In neither case were the Applicants required to submit a Sequence Listing.

The Applicants hereby petition under 37 C.F.R. § 1.183 that the Sequence Listing requirement, as applied by M.P.E.P. 2421.01, be waived with respect to the present application. M.P.E.P. 2421.01 states in pertinent part:

The sequence rules require the use of standard symbols and a standard format for sequence data in <u>most</u> sequence-type patent applications. They further require the submission of that data in computer readable form. Compliance is required for <u>most</u> disclosures of sequence data in new applications filed on or after October 1, 1990.

In <u>exceptional circumstances</u>, it should be noted that the Office may waive the rules via a 37 CFR 1.183 petition. (Emphasis added)

As indicated above, M.P.E.P. 2421.01 does not require that the Sequence Listing Rules be applied to ALL new applications filed on or after October 1, 1990. Instead, the Sequence Listing Rules may be waived with respect to a new application where "exceptional circumstances" exist. For the reasons stated below, the Applicants respectfully submit that "exceptional circumstances" under M.P.E.P. 2421.01 exist such that the Sequence Listing Rules should be waived with respect to the present application.

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## 1. Exceptional Circumstances - To provide a Sequence Listing would be unduly burdensome and a hardship

The Applicants respectfully submit that requiring the present application to comply with the Sequence Listing Rules would place undue hardship on the Applicants. The sequence data found in the present application is currently not available in any computer readable form because the PCT application from which the present application ultimately arose was filed in 1991 and was not subject to the Sequence Listing Rules. Hence, neither a paper nor computer readable sequence listing was prepared. Because the sequence data found in the present application is not available in computer readable form, the Applicants would have to manually enter and format numerous peptide and nucleotide sequences which would require a huge expenditure of time and expense without providing commensurate benefit to either the U.S. Patent & Trademark Office or the public especially in view of the fact that none of the sequences are being claimed (nor were they claimed in the parent or grandparent applications). Further, amending the specification and the drawings to recite SEQ ID NOS, would add to the excessive burden particularly in view of the complexity and length of the specification and in fact may result in the necessity of filing a second "substitute specification" for this application, which in turn would add to the Examiner's burden in examining this application.

Furthermore, Applicants respectfully submit that the allowance and issuance of the parent and grandparent applications described above indicate that sequence information contained therein was in a format that allowed appropriate searches to be made and which allowed the Draftsman to accurately present the disclosed sequences, both of which underlie the rationale for requiring sequence listings. *See* M.P.E.P. 2420.

Because manually entering and formatting the sequence data found in the present application as well as amending the specification, preparing new drawings, and the possibility of having to prepare a second substitute specification would be excessively time consuming, prohibitively expensive, and without commensurate benefit to the Patent Office or the public, the Applicants respectfully request that the Sequence Listing Rules be waived with respect to the present application.

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## **CONCLUSION**

In view of the foregoing, the Applicants believe that because of the "exceptional circumstances" described herein, the Sequence Listing Rules may be properly waived with respect to the present application and waiver is hereby requested.

The Commissioner is hereby authorized to charge any additional fees which may be required in this application to Deposit Account No. 50-1214.

Respectfully submitted,

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